

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration Washington, DC

NOV 3 1999

Mr. Jonathan W. Emord Emord & Associates, P.C. 1050 Seventeenth Street, N.W. Suite 600 Washington, DC 20036

Re: Docket Nos. 98N-0419, 98N-0421, 98N-0422, 98N-0423, 98N-0424, 98N-0426, 98N-0427, 98N-0428

## Dear Mr. Emord:

This letter responds to your citizen petitions dated March 11, 1999, submitted on behalf of the American Preventive Medical Assoication, Pure Encapsulations, Inc., Weider Nutrition International, Inc., and Julian M. Whitaker, M.D., requesting that the Food and Drug Administation (FDA) revoke the following eight interim final rules: 1) "Food Labeling: Health Claims; Omega-3 Fatty Acids and the Risk in Adults of Cardiovascular Disease," 63 FR 34107, June 22, 1998 (Docket No. 98N-0419); 2) "Food Labeling: Health Claims; Zinc and the Body's Ability to Fight Infection and Heal Wounds in Adults," 63 FR 34112, June 22, 1998 (Docket No. 98N-0421); 3) "Food Labeling: Health Claims: Garlic, Reduction of Serum Cholesterol, and the Risk of Cardiovascular Disease in Adults," 63 FR 34110, June 22, 1998 (Docket No. 98N-0422); 4) "Food Labeling: Health Claims; Calcium Consumption by Adolescents and Adults, Bone Density and The Risk of Fractures," 63 FR 34101, June 22, 1998 (Docket No. 98N-0423); 5) "Food Labeling: Health Claims; Chromium and the Risk in Adults of Hyperglycemia and the Effects of Glucose Intolerance," 63 FR 34104, June 22, 1998 (Docket No. 98N-0424); 6) "Food Labeling: Health Claims; Antioxidant Vitamins C and E and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, Certain Cancers, and Cataracts," 63 FR 34084, June 22, 1998 (Docket No. 98N-0426); 7) "Food Labeling: Health Claims, B-Complex Vitamins, Lowered Homocysteine Levels, and the Risk in Adults of Cardiovascular Disease," 63 FR 34097, June 22, 1998 (Docket No. 98N-0427), 8) "Food Labeling: Health Claims; Antioxidant Vitamin A and Beta-Carotene and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, and Certain Cancers," 63 FR 34092, June 22, 1998 (Docket No. 98N-0428).

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In accordance with Title 21 of the Code of Federal Regulations (21 CFR) 10.30(e)(3), this letter is to advise you of the action that FDA is taking on your petitions. We are converting your petitions to comments to the interim final rules. Each petition has been submitted to the docket number corresponding to the appropriate interim final rule and will become part of the administrative record for that rulemaking. They will be carefully considered by the agency in its deliberations on what action to take concerning the interim final rules.

Sincerely,

Elizabeth A. Yetley, Ph.D.

Director

Office of Special Nutritionals

Center for Food Safety and Applied Nutrition

## **CROSS FILE SHEET**

File Number: 98N-0419/ANS3

See File Number: 98N 0421/ANS3

98N<sub>7</sub>0422/ANS3

98N-0423/ANS3

98N+0424/ANS3

98N+0426/ANS3

98N-0427/ANS3

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